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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,623	03/10/2004	Edward I. Wulfman	89000.3013NP	6167
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EXAMINER				
WEBB, SARAH K				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/798,623

Applicant(s)

WULFMAN ET AL.

Examiner

SARAH WEBB

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 2-5, 10, 17, 19, 20 and 22-28 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 2-5, 10, 17, 19, 20 and 22-28 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-886)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date ____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pages 1-5, filed 10/27/2011, with respect to the rejection(s) of claim(s) 19 and 20 under Nash et al. (US 6,080,170) in view of Zacca et al. (US 5,217,474), have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Zacca et al. in view of Nash et al. Zacca discloses the concept of delivering fluids to an "intersect area" of an atherectomy device proximal to its cutting head. Nash discloses the combination of fluid delivery and fluid aspiration systems of an atherectomy device. Nash provides proper motivation to modify Zacca to include an aspiration catheter with a sealed site in the housing, as Nash teaches that providing aspiration to the treatment site prevents the particulates from flowing to other areas of the vasculature.
2. Applicant presented arguments that Nash fails to that the sealing site (326) at the proximal end of the liner (34) is not enclosed by the housing. For clarification, all the components illustrated in Figure 13 are enclosed by the housing (400) shown in phantom lines in Figure 9A (column 24, line 60-column 25). Therefore, Nash teaches that the proximal end of the liner (34) is enclosed within the housing (400) and in sealed fluid communication with the infusion port (86). (Infusion port 86 is located toward middle of housing 400 and portion 322 is *within* housing 400 in Figure 9A).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2-5, 10, 17, 19, 20, 22-24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,217,474 (Zacca et al.) in view of US Patent No. 6,080,170 (Nash et al.).

Zacca discloses an atherectomy assembly that includes rotatable torque tube (8), a cutting head (16) at its distal end, and a drive assembly (1) at the proximal end. A liner (14) surrounds the torque tube (8) and forms a liquid flood space (34) between the two components into which cooling or contrast fluids may flow from infusion port (3)(column 6, lines 40-46). A housing (9) surrounds the proximal ends of the torque tube (8) and liner (14) (column 5, lines 58-62). Liquid is supplied through an infusion port (3), through a sealing site in the housing (9), and into the liquid flood space, or annular space (34) between the torque tube and liner (column 6, lines 30-34 and 38-52). Although not explicitly shown, it is understood that the liner (14) extends proximally into the housing (9) to the location of the infusion port (3) so that liquid may be introduced into its lumen. Therefore, the housing (9) is considered to meet the requirement that it provides a "sealing site". As best shown in Figure 2, Zacca the liner (14) extends from the sealing site in the housing longitudinally less than the length of

the torque tube (8) to create an "intersect area" at the terminal location of the liner (14). This "intersect area" is proximal of the working head (16).

Zacca fails to include an aspiration catheter that encloses the torque tube and liner and provides an aspiration lumen. Nash discloses another atherectomy device in Figure 9A-13 that includes a rotatable torque tube (308 and 336) attached to a drive system (322) at its proximal end and a working head (32") at its distal end. Similar to Zacca, a liner (22') surrounds the torque tube (308) and forms a "liquid flood space" between their surfaces to deliver fluids to the area of the working head (column 8, lines 48-59; column 10, lines 4-13). The flow of liquids from the flood space is indicated by arrows (Q1) in Figures 2 and 3. Nash teaches that an aspiration catheter (24) should be included in the system for removing the fluids and loosened occlusive particles from the blood stream, as indicated by arrows (Q2) in Figures 2 and 3 (column 9, lines 5-10; column 10, lines 20-50). The aspiration catheter (24) encloses the atherectomy torque tube and liner, and an aspiration lumen is defined between the outer catheter (24) and the liner (22') (column 16, lines 35-44). In addition to an infusion port (86) that is in communication with the flood space between the torque tube (336/308) and liner (34), a housing (400 shown in phantom lines in Figure 9A), comprises an aspiration port (88) in communication with an aspiration site at the proximal end of the catheter (24). Figure 13 shows greater detail of the attachment of the torque tube (308 and 336) to a drive system (turbine 338) within the housing and a sealing site (326) at the proximal end of the stationary liner (34) within the housing (400) (column 24, line 60-column 25). It would have been obvious to one of ordinary skill in the art to enclose the atherectomy

device of Zacca with an aspiration catheter, as taught by Nash, in order to provide a means for removing debris from the treatment site and preventing it from flowing into other areas of the bloodstream.

Although Zacca does not go into specific detail regarding the connection between the infusion port (3) and the "liquid flood space", Nash teaches that the infusion port (86) at the proximal end of the liner should be a sealed site within the housing (400) (column 10, lines 330; column 22, line 64 to column 23, line 38; columns 24-25). It would have been further obvious to configure the modified Zacca device to include a sealing site within the housing for providing a fluid-tight pathway in communication liquid flood space at the proximal end of the liner.

The modified Zacca device includes all the claimed components and is *capable of functioning as a "liquid seal assembly."* The language *"a catheter...extending distally to enclose the torque tube and the liner"* in lines 11-12 of claim 19 and section (c) of claim 20 is a recitation of the relative position of two moveable components. Therefore, it is considered to be functional language that is not given full patentable weight. The prior art is not required to disclose this relative position, but merely have the *capability* of being manipulated in this way to meet the claims limitations. The outer catheter of the modified Zacca apparatus is *capable of* being moved to a position where its distal end extends beyond the distal end of the liner at the "intersect area." This relative position is broad enough to encompass a location where the distal end of the catheter is distal to the liner but proximal to the working head during its operation. Nash discloses that liquid exiting from the "intersect area" at the distal end of the liner (Q1) is drawn into

the aspiration catheter by suction (Q2). Therefore, liquid exiting from the flood space (34) of the modified Zacca device is capable of being directly pulled into the aspiration lumen. Therefore, the modified Zacca apparatus meets the functional requirements of claims 19 and 20.

Regarding claim 3, the Zacca drive shaft (8) is a coiled drive shaft and the flood space (34) includes any gaps between the coils (column 5, lines 42-65). Nash describes a helical torque tube (308) that meets the requirement of "coiled drive shaft" and mentions gaps in between the coils (column 23, lines 39-50).

Regarding claim 4, Zacca includes a lumen (64) in a guidewire (12) is received (Figure 1; column 7, lines 6-11). Nash discloses a guide wire (124) used with the system and a guide wire lumen shown passing through the torque tube in Figure 12.

Regarding claim 5, Nash discloses that the aspiration port (88) serves as a suction port for removing fluid from the aspiration lumen. The recitation of specific working pressures along the length of the device is not given full patentable weight, as it is a recitation of the intended use of the device. The infusion and aspiration pressures are capable of being adjusted as desired to create a lower pressure in the flood space (column 10), so the modified Zacca assembly meets this claim.

Regarding claim 10, Nash discloses that the housing may include additional ports (such as connection of shaft 336 with bearing 350; ports 24A and B in Figures 10 and 11; port 360 in Figure 13) that are capable of functioning as "overflow ports."

Regarding claim 17, both handles of Zacca and Nash are hand held units.

Regarding claims 22 and 23, Zacca discloses that the drive shaft coil (8) may have a diameter as small as 0.032 inches (column 6, line 2), but is silent with respect to dimensions of the liner. Nash discloses that the liner (34) has an outside diameter of 1.5mm (0.059 inch) (column 8, line 5), but is silent with respect to the inside diameter and length. It would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the liner of the modified Zacca device to have an inner diameter of about 0.03 inch to 0.04 inch and a length of about 6 inches, as a mere change in size of a component is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Regarding claim 24, Zacca is silent with respect to the material of the liner, but states that it should be a suitable biocompatible material (column 5, lines 48-50). Nash teaches that the liner (34) should be made of plastic (column 8, line 3), which is considered to meet the requirements of thin, tough, flexible, and polymer-based tubing. It would have been obvious to form the liner of the modified Zacca device from plastic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 26, Nash discloses that the torque tube can be axially translated by moving handle (416) (column 25, lines 27-42).

Regarding claim 27: Although Nash is silent with respect to the selection of the length and diameter of the liner for the purpose of reducing flow rate and requirement for precise diametrical tolerances, it would have been obvious to optimize the relative

dimensions of the liner since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

4. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zacca et al. in view of Nash et al., as applied to claims 19 and 20 above, and further in view of US Patent No. 6,258,052 (Milo).

Nash discloses that the liner (34) is plastic and discloses the use of anti-friction sleeves over components of the system (column 13, line 43), but Nash and Zacca fail to specify that the liner comprises polyimide tubing with a lubricious coating. Milo teaches that forming a liner over a coiled shaft from a polyimide tube increases pushability and column strength (col. 2, ln. 61 - col. 3, ln. 2). It would have been obvious to one of ordinary skill to form the modified Nash liner from a polyimide material with a lubricious coating, as it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Webb whose telephone number is (571)272-5749. The examiner can normally be reached on Monday through Friday from 9:00 AM-5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Tom Hughes, at (571) 272-4357.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. W./
Examiner, Art Unit 3731

/Kathleen Sonnett/
Primary Examiner, Art Unit 3731